DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 23, 2017

LR Med Inc
% Mr. Richard Keen
VP Operations
Compliance Consultants
1151 Hope Street
Stamford, Connecticut 06907

Re: K171188
Trade/Device Name: Ossler Exam Scope, Model OS100
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, FLL, DRG, ERA
Dated: March 27, 2017
Received: April 24, 2017

Dear Mr. Richard Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171188

Device Name
Ossler Exam Scope, Model OS100

Indications for Use *(Describe)*

Ossler Exam Scope, Model OS 100 is indicated to detect and amplify heart, lung, and other body sounds as well as to measure body temperature for infants and adults for diagnostic or monitoring purposes on a patient where by the patient will benefit by uploading these data for diagnostic consultation. This does shall not be prescribed for "active patient monitoring".

Contraindications
Ossler Exam Scope, Model OS 100 shall not be used in a clinical condition requiring an immediate clinical response. Ossler Scope shall not be for active patient monitoring.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Summary

23 June 2017

Sponsor	**Consultant**
Dr. Prashant Deshpande	Mr. Richard Keen
LR Med Inc,	Compliance Consultants
a/k/a GALENUS SCIENTIFIC	1151 Hope Street
1450 Tomlin Drive	Stamford, CT 06907-1659
Burr Ridge, IL 60527	203 329 2700 F 203 329 2345
708 903 0100	rkeen@fda-complianceconsultants.com
prashantd@galenus-scientific.com	

Proprietary Name:	Ossler Exam Scope , Model OS100
Common Name	Exam scope
Device Classification Name	Exam scope surgical instrument for use in general and plastic surgery and in dermatology.
Classification Number:	21 CFR 870. 1875 & 21 CFR 880. 2910
Product Code	DQD & FLL
Reviewing Group	Cardiac Diagnostics Devices
Device Classification	Class II
Establishment registration No.	N/A
Predicate Device	K120704 3M Littman® TeleSteth Online Auscultation System K131243 Model JPD-FR100

Device Description

The ***Ossler Exam Scope , Model OS100*** is prescribed by a physician to be used by an operator to conduct a limited, examination session to upload heart sounds, lung sounds, temperature, calibrated images of the skin, tonsils, ears, and upload this data to a remote expert for diagnosis. This device is designed to deliver, to a health care provider, the physiological sensory date collected from a remote location. The healthcare provider then makes a diagnostic decision using this data. When the health care provider deems that collection of data provides benefits to the patient and health care provider.

The ***Ossler Exam Scope*** ^{tm} provides a facility where the patient is remote from health care provider and key physiological inputs are required. Usually a health care provider is placed in the difficult position of making a decision with poor descriptions and little or no real information. With the rise of cell phones, many APPs are created to attempt to develop physiological data. The ***Ossler Exam Scope , Model OS100*** is completely different. At the heart of this device is the founder's goal to conduct an exam at the point of care and measure physiological conditions to develop reliable, sophisticated inputs that can be delivered remotely to a qualified expert for diagnosis.

This device does not affect how physicians "practice medicine". As a prescription device, the physician still conducts an exam and then reaches a diagnostic decision. The only significant change is to the BENEFIT of the patient, it reduces the obstacles necessary for the patient to present to the physician.

Summary

The RISKs are reduced since this device uses far better Class II instruments than other stethoscopes and infrared thermometers. Features of the *Ossler Exam Scope.* This compact, hand held device embodies expert sensors to detect physiological data at the point of patient care. Each sensor is tested for diagnostic performance unlike the usual cell phone devices from the internet.

The Ossler Exam Scope, Model OS100 features a stethoscope, camera, thermometer and Otoscope. Contained within a comfortable, durable case, it features a display screen where the user can view the menu and make selections to complete an exam session. Upon completion the device can connect and upload data via WiFi for expert diagnosis. The Exam Scope uses reliable commercial quality embedded microprocessors with a rechargeable battery. The driving firmware is of course custom designed to meet the challenges of this sophisticated diagnostic device.

Indications for Use
Ossler Exam Scope, Model OS 100 is indicated to detect and amplify heart, lung, and other body sounds as well as to measure body temperature for infants and adults for diagnostic or monitoring purposes on a patient where by the patient will benefit by uploading these data for diagnostic consultation. This does shall not be prescribed for "active patient monitoring".

Contraindications
Ossler Exam Scope, Model OS 100 shall not be used in a clinical condition requiring an immediate clinical response. Ossler Scope shall not be for active patient monitoring.

Intended Use
Ossler Scope - OSC10 is intended for use as a handheld examination scope to provide temperature, heart/lung sounds during a diagnostic session.

The **scientific concept** on which this device is based, is the principle that expert, qualified data from a stethoscope and thermometer will aid a physician in making a diagnostic decision when this data is necessary and the patient is not in the same room as the physician. This device **functions** by delivering heart sounds, lung sounds, temperature, calibrated images of the skin, tonsils, ears, and upload this data to a remote expert for diagnosis.

Benefits
This device offers a benefit to those patients who cannot be present to their physician when the data this device provides can assist the physician. The ***Ossler Exam Scope*** ^{tm} offers the practitioner a better alternative than depending on the growing availability of data from unqualified devices such as cell phones.

Risk
The risks associated with conducting an exam with a patient using this device and achieving a false presentation of data is almost non-existence.

Summary

Technical Characteristics

The ***Ossler Exam Scope*** [tm] uses the same technical characteristics as the two cleared predicate Class II devices: stethoscope & thermometer(IR non-contact). The technical characteristics of the stethoscope use a collection cavity to measure vibrations that are amplified and digitized. The thermometer functions by collecting reflected infrared energy into a thermopile and counting and digitizing the data.

Substantial Equivalence

LR Med Inc, a/k/a Galenus Scientific has determined that the ***Ossler Exam Scope , Model OS100*** is substantially equivalent to the performance of two earlier predicates. A stethoscope predicate and an IR thermometer predicate. The following compares feature of the stethoscope in this device to the predicate stethoscope and the features of the infrared thermometer of this device to the infrared thermometer of the predicate.

This table compares the principal elements of the stethoscope features to the predicate stethoscope.

Description/ Feature	K171188 GALENUS SCIENTIFIC Ossler Exam Scope	predicate device Littman K120704
Distribution	prescription	prescription
Interfaces	Lineout audio interface for Standard off-the shelf headphones with 3.5mm jack	standard, off-the shelf Headset with a 3.5 mm stereo audio plug
three filter frequency modes	Bell (20-200Hz), Diaphragm (200-500Hz) Wide (20-800Hz).	overall auscultation frequency response is 20 Hz - 1,500 Hz
Handheld	Yes	Yes
Battery operated	Yes	Yes
Computer driven	Yes	Yes
Display	Yes	Yes
Calibrated accuracy	Yes	Yes
Age of patients	Adults and infants	Adults and infants
Patient Condition: Ambulatory	Yes	Yes

This table compares the principal elements of the thermometer features to the predicate thermometer.

Description/ Feature	new device GALENUS SCIENTIFIC Ossler Exam Scope	predicate device K131243 Model JPD-FR100
Distribution	prescription	over the counter
Measuring Range	34.4°C (94°F) thru 42.2°C (108°F)	32.2º C to 43.3 2º C 90.0ºF to 109.9ºF
Accuracy	+/- 0.3°C	±0.2ºC (0.4ºF)
measurement location	forehead	forehead
Handheld	Yes	Yes
Battery operated	Yes	Yes
Computer driven	Yes	Yes
Display	Yes	Yes
Calibrated accuracy	Yes	Yes
Age of patients	Adults and infants	Adults and infants
Patient Condition: Ambulatory	Yes	Yes

Summary

Performance Data that supports Substantial Equivalence		
Performance Data	Stethoscope K120704 3M Littman® TeleSteth Online Auscultation System	Thermometer K131243 Model JPD-FR100
Ability to measure the same physiological parameters	tested	tested
Ability to provide same utility to users	tested	tested
Ability to offer the same features	tested	tested

Non-clinical Testing

The Ossler Exam Scope , Model OS100 has had the benefit of Verification, Validation and Safety testing to Harmonized Standards (IEC-60601-1, IEC-60601-2 and IEC-60601-11). These Performance Tests were conducted:

1. System Verification & Validation Test Procedure & Record
2. Thermometer Subsystem Verification & Validation Test Procedure & Record
3. Stethoscope Subsystem Verification & Validation Test Procedure & Record
4. Display and Communication Verification & Validation Test Procedure & Record
5. Safety Test Procedure & Record
6. Usability Study at a recognized, independent simulation usability organization.

Usability Study under controlled boundaries

A usability study was conducted by a specialized independent research group. A study population sample size was carefully selected by reading the Ossler Exam Scope User Manual to understand the challenges. It was determined that only people who were familiar with using a smart phone would be able to collect a temperature and stethoscope reading. After the selected users completed the assignment, results were tabulated and deficiencies in the User Instructions were incorporated. Then a different group of users completed the assignment using the revised instructions and all demonstrated the ability to capture the intended information.

Performance Testing

The ***Ossler Exam Scope , Model OS100*** has undergone a battery of non-recurring, recurring and interface tests that verify operation as intended. These test results serve to confirm that the ***Ossler Exam Scope , Model OS100*** does not raise any new issues of safety or effectiveness.

Verification testing was conducted on prototypes. Validation testing was conducted on a released version of the ***Ossler Exam Scope, Model OS100.*** All testing benefited from formal, controlled specifications and procedures. Subsequent to that activity, relevant harmonized testing IEC 60601-1 and 60601-2 60601-11 was performed. This testing was performed by a recognized third party test laboratory.

Usability Testing

The ***Ossler Exam Scope , Model OS100***, has benefited from design, development, testing procedures that conform to Quality Systems. Testing has confirmed this device meets its product specification. A usability study was performed to establish the device can present the data stated in the indications for use to users who follow the user manual.